ATTACHMENT D

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ERIC MCARTHUR and JENNY MCARTHUR, Proceeding on their own behalf and on Behalf of their minor child, M.M., *Plaintifs,* v. SCOTT BRABRAND, *et. al.,* *Defendants,*	Civil Action No.: 3 :21-cv-00317

DECLARATION OF DR. JAYANTA BHATTACHARYA

I, Dr. Jayanta Bhattacharya, declare as follows:

1. I am an adult of sound mind and make this statement voluntarily, based upon my knowledge, education, and experience.

EXPERIENCE & CREDENTIALS

2. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine and a research associate at the National Bureau of Economic Research. I am also Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 155 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed scientific literature more than 12,400 times. My curriculum vitae is attached to this declaration as Exhibit A.

3. I have dedicated my professional career to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions. I have studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). I am intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.

4. My assessment of vaccine immunity is based on studies related to the efficacy and safety of the one vaccine to receive full approval from the Food and Drug Administration (FDA) and the two vaccines for which the FDA has granted Emergency Use Authorization (EUA) for use in the United States. These include two mRNA-technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus-vector vaccine technology (manufactured by Johnson & Johnson). Of those, the Pfizer vaccine, also known as Comirnaty, has full FDA approval.

5. I have not and will not receive any financial or other compensation to prepare this Declaration or to testify in this case. Nor have I received compensation for preparing declarations or reports or for testifying in *any* other case related to the COVID-19 pandemic or any personal or research funding from any pharmaceutical company. My participation here has been motivated solely by my commitment to public health, just as my involvement in other cases has been.

6. I have been asked to provide my opinion on several matters related to vaccine mandates:

- Whether, based on the current medical and scientific knowledge, immunity after COVID recovery (sometimes referred to as natural immunity) is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus;

- Whether, based on the existing medical and scientific understanding of SARS-CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity;

- Whether there is scientific evidence to support determinations that immunity provided by COVID recovery should not be considered as a reason to be excused from vaccine mandates.

I can summarize my opinions briefly. The scientific evidence strongly indicates that the recovery from COVID disease provides strong and lasting protection against severe disease if reinfected, at least as good and likely better than the protection offered by the COVID vaccines. While the COVID vaccines are effective at protecting vaccinated individuals against severe disease, they provide only short-lasting and limited protection versus infection and disease transmission. Requiring vaccines for COVID recovered patients thus provides only a limited benefit while exposing them to the risks associated with the vaccination.

OPINIONS

I. COVID-19 Infection Fatality Risk

1. SARS-CoV-2, the virus that causes COVID-19 infection, entered human circulation some time in 2019 in China. The virus itself is a member of the coronavirus family of viruses, several of which cause typically mild respiratory symptoms upon infection. The SARS-CoV-2 virus, by contrast, induces a wide range of clinical responses upon infection. These presentations range from entirely asymptomatic infection to mild upper respiratory disease with unusual symptoms like loss of sense of taste and smell, hypoxia, or a deadly viral pneumonia that is the primary cause of death due to SARS-CoV-2 infection.

2. The mortality danger from COVID-19 infection varies substantially by age and a few chronic disease indicators.[1] For most of the population, including the vast majority of children and young adults, COVID-19 infection poses less of a mortality risk than seasonal influenza. By contrast, for older people – especially those with severe comorbid chronic conditions – COVID-19 infection poses a high risk of mortality, on the order of a 5% infection fatality rate.

3. The best evidence on the infection fatality rate from SARS-CoV-12 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people in a population who have specific antibodies against SARS-CoV-2 in their bloodstream. A seroprevalence study measures the fraction of a population who have antibodies that are produced specifically by people infected by the SARS-CoV-2 virus. The presence of specific antibodies in blood provides excellent evidence that an individual was previously infected.

4. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts. PCR tests are the most common type of test used to check whether a person currently has the virus or viral fragments in their body (typically in the nasopharynx). The PCR test should not be used to count the total number of people who have been infected to date in a population. Case reports and PCR test counts both miss infected people who are not identified by the public health authorities or who do not volunteer for RT-PCR testing. That is, they miss people who were infected but recovered from the condition without coming to the attention of public

[1] Public Health England (2020) Disparities in the Risk and Outcomes of COVID-19. August 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/908434/Disparities_in_the_risk_and_outcomes_of_COVID_August_2020_update.pdf

health authorities. Because they ignore unreported infections, fatality rate estimates based on case reports or positive test counts are substantially biased toward reporting a higher fatality rate.

5. According to a meta-analysis[2] by Dr. John Ioannidis of every seroprevalence study conducted to date of publication with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate—the inverse of the infection fatality rate—from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%. A separate meta-analysis[3] by other scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.

6. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in *The Lancet*)[4] provides a detailed age breakdown of the infection survival rate in a preprint companion paper[5] 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65.

7. I estimated the age-specific infection fatality rates from the Santa Clara County seroprevalence study[6] data (for which I am the senior investigator). The infection survival rate is 100% among people between 0 and 19 years (there were no deaths in Santa Clara in that age range up to that date); 99.987% for people between 20 and 39 years; 99.84% for people between 40 and 69 years; and 98.7% for people above 70 years.

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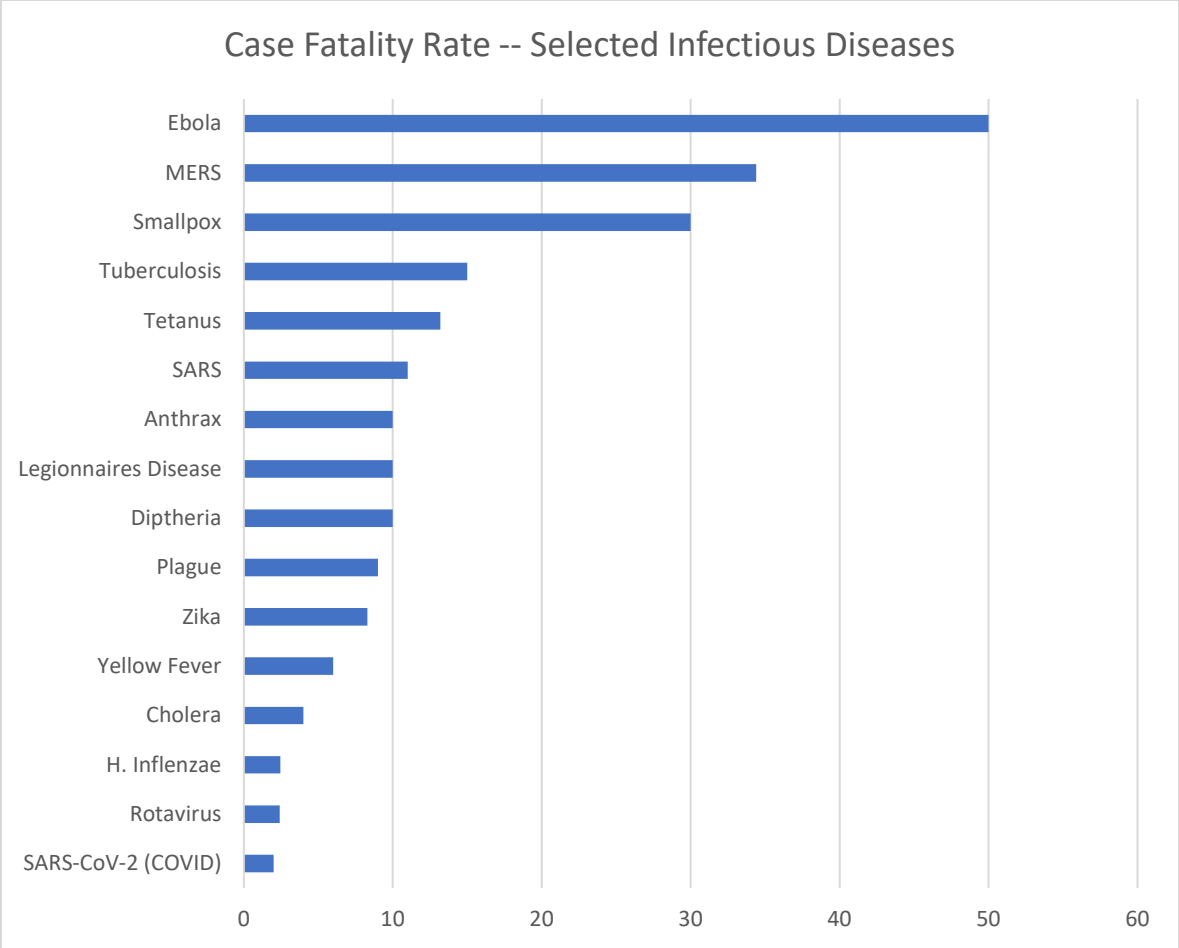
[2] John P.A. Ioannidis , *The Infection Fatality Rate of COVID- 19 Inferred from Seroprevalence Data*, Bulletin of the World Health Organization BLT 20.265892.
[3] Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rate for COVID- 19: Meta-Analysis & Public Policy Implications* (Aug. 14,2020)MEDRXIV, http://bit.ly/3gplolV.
[4] Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 lgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study* (June 11, 2020) THE LANCET, https://bit.ly/3187S13.
[5] Francisco Perez-Saez, et al. *Serology- Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland* (June 15,2020) OSF PREPRINTS, http://osf.io/wdbpe/.
[6] Eran Bendavid, et al., *COVID- 19 Antibody Seroprevalence in Santa Clara County, California* (April 30,2020) MEDRXIV, https://bit.ly/2EuLIFK.

8. Those numbers are consistent with what the US CDC has reported. A US CDC report[7] found between 6 and 24 times more SARS-CoV-2 infections than cases reported between March and May 2020. Correspondingly, the CDC's estimate of the infection fatality rate for people ages 0-19 years is 0.003%, meaning infected children have a 99.997% survivability rate. For people ages 20-49 years, it was 0.02%, meaning that young adults have a 99.98% survivability rate. For people age 50-69 years, it was 0.5%, meaning this age group has a 99.5% survivability rate. Finally, for people ages 70+ years, it was 5.4%, meaning seniors have a 94.6% survivability rate. [8] There is thus no substantial qualitative disagreement about the infection fatality rate reported by the CDC and other sources in the scientific literature. This should come as no surprise since they all rely on seroprevalence studies to estimate infection fatality rates.

9. It is helpful to provide some context for how large the mortality risk is posed by COVID infection relative to the risk posed by other infectious diseases. Since seroprevalence-based mortality estimates are not readily available for every disease, in the figure immediately below, I plot case fatality rates, defined as the number of deaths due to the disease divided by the number of identified or diagnosed cases of that disease. The case fatality rate for SARS-CoV-2 is ~2% (though that number has decreased with the availability of vaccines and effective treatments). By contrast, the case fatality rate for SARS is over five times higher than that, and for MERS, it is 16 times higher than that.

[7] Fiona P. Havers, et al., *Seroprevalence of Antibodies to SARS-CoV-2 in 10 Sites in the United States, March 23-May 12, 2020* (Jul. 21, 2020) JAMA INTERN MED., https://bit.ly/3goZUgy.
[8] COVID- 19 Pandemic Planning Scenarios, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.



10. Perhaps the most important implication of these estimates is that they identify two distinct populations of people who face a very different risk from COVID infection. One segment – the elderly and others with severe chronic disease – faces a higher risk of mortality if infected (especially if unvaccinated). A second segment – typically non-elderly people – face a very low risk of mortality if infected and instead face much greater harm from lockdowns, school closures, and other non-pharmaceutical interventions than from COVID infection itself. The right strategy, then, is focused protection of the vulnerable population by prioritizing them for vaccination while lifting lockdowns and other restrictions on activities for the rest since they cause harm without corresponding benefit for the non-vulnerable. The Great Barrington Declaration, of which I am a primary co-author, describes an alternate policy of focused protection. This policy would lead to

fewer COVID-related deaths and fewer non-COVID-related deaths than universal lockdowns or a strategy that lets the virus rip through the population. My co-authors of this Declaration include Prof. Martin Kulldorff of Harvard University and Prof. Sunetra Gupta of Oxford University. Over 15,000 epidemiologists and public health professionals and 50,000 medical professionals have co-signed the Declaration.[9]

11. The infection fatality rate estimates presented in this section are drawn from data before widespread vaccination in the U.S. and elsewhere. The COVID-19 vaccines approved for use in the U.S. are very effective in substantially reducing the infection fatality rate. According to the US Centers for Disease Control, the mRNA vaccines were 94% effective against COVID-19 hospitalization for patients 65 and older.[10] So, the infection fatality rates that I provide above are overestimated by at least one order of magnitude. Fully vaccinated, non-elderly professors in classrooms face a vanishingly small risk of mortality even if the SARS-CoV-2 virus infects them.

II. Natural Immunity Provides Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected; COVID-19 Vaccines Provide Limited Protection Against Infection but Durable Protection Against Severe Outcomes if Infected.

12. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There is no reason to presume that vaccine immunity provides a higher level of protection than natural immunity. Since vaccines arrived one year after the disease, there is stronger evidence for long-lasting immunity from natural infection than from the vaccines.

13. Both types of immunity are based on the same basic immunological mechanism—

[9] Bhattacharya J, Gupta S, Kulldorff M (2020) Great Barrington Declaration. https://gbdeclaration.org
[10] Tenforde MW, Olson SM, Self WH, et al. Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Among Hospitalized Adults Aged ≥65 Years — United States, January–March 2021. MMWR Morb Mortal Wkly Rep 2021;70:674–679. DOI: http://dx.doi.org/10.15585/mmwr.mm7018e1external icon

stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibody levels in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.[11,12] A Phase III trial showed 85% efficacy for the Johnson & Johnson adenovirus-based vaccine against severe disease.[13]

14. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B cells,[14] bone marrow plasma cells,[15] spike-specific neutralizing

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[11] Baden, L. R., El Sahly, H. M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S. A., Rouphael, N., Creech, C. B., McGettigan, J., Khetan, S., Segall, N., Solis, J., Brosz, A., Fierro, C., Schwartz, H., Neuzil, K., Corey, L., Zaks, T. for the COVE Study Group (2021). Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine*, *384*(5), 403-416. doi: 10.1056/NEJMoa2035389

[12] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W. Jr., Hammitt, L. L., Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine*, *387*(27), 2603-2615. doi: 10.1056/NEJMoa2034577

[13] Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P. A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K. L., Robb, M. L., Treanor, J., Barouch, D. H., Stoddard, J., Ryser, M. F., Marovich, M. A., Douoguih, M. for the ENSEMBLE Study Group. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *The New England Journal of Medicine*, *384*(23), 2187-2201. doi: 10.1056/NEJMoa2101544

[14] Dan, J. M., Mateus, J., Kato, Y., Hastie, K. M., Yu, E. D., Faliti, C. E., Grifoni, A., Ramirez, S. I., Haupt, S., Frazier, A., Nakao, C., Rayaprolu, V., Rawlings, S. A., Peters, B., Krammer, F., Simon, V., Saphire, E. O., Smith, D. M., Weiskopf, D., Crotty, S. (2021). Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science*, *371*, 1-13. doi: 10.1126/science.abf4063 (finding that memory T and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility in most individuals").

[15] Turner, J. S., Kim, W., Kalaidina, E., Goss, C. W., Rauseo, A. M., Schmitz, A. J., Hansen, L., Haile, A., Klebert, M. K., Pusic, I., O'Halloran, J. A., Presti, R. M. & Ellebedy, A. H. (2021). SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. *Nature*,

antibodies,[16] and IgG+ memory B cells[17] following naturally acquired immunity.

15. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies overwhelmingly conclude that natural immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

16. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19[18] and show that the vast majority of reinfections are less severe than first-time

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595(7867), 421-425. doi: 10.1038/s41586-021-03647-4 (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Callaway, E. (2021, May 26). Had COVID? You'll probably make antibodies for a lifetime. *Nature*. https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

[16] Ripperger, T. J., Uhrlaub, J. E., Watanabe, M., Wong, R., Castaneda, Y., Pizzato, H. A., Thompson, M. R., Bradshaw, C., Weinkauf, C. C., Bime, C., Erickson, H. L., Knox, K., Bixby, B., Parthasarathy, S., Chaudhary, S., Natt, B., Cristan, E., El Aini, T., Rischard, F., Bhattacharya, D. (2020). Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humor immunity. *Immunity*, *53*(5), 925-933. doi: 10.1016/j.immuni.2020.10.004 (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

[17] Cohen, K. W., Linderman, S. L., Moodie, Z., Czartoski, J., Lai, L., Mantus, G., Norwood, C., Nyhoff, L. E., Edara, V. V., Floyd, K., De Rosa, S. C., Ahmed, H., Whaley, R., Patel, S. N., Prigmore, B., Lemos, M. P., Davis, C. W., Furth, S., O'Keefe, J., McElrath, M. J. (2021). Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *medRxiv*, Preprint. (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

[18] Shrestha, N. K., Burke, P. C., Nowacki, A. S., Terpeluk, P. & Gordon, S. M. (2021). Necessity of COVID-19 vaccination in previously infected individuals. *medRxiv*, Preprint. doi: 10.1101/2021.06.01.21258176 ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study" and concluded that those with natural immunity are "unlikely to benefit from COVID-19 vaccination"); Perez, G., Banon,

infections.[19] For example, an Israeli study of approximately 6.4 million individuals demonstrated

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T., Gazit, S., Moshe, S. B., Wortsman, J., Grupel, D., Peretz, A., Tov, A. B., Chodick, G., Mizrahi-Reuveni, M., & Patalon, T. (2021). A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: A preliminary report. *medRxiv*, Preprint. doi: 10.1101/2021.03.06.21253051 (Israeli study finding that approximately 1/1000 of participants were reinfected); Bertollini, R., Chemaitelly, H., Yassine, H. M., Al-Thani, M. H., Al-Khal, A., & Abu-Raddad, L. J. (2021). Associations of vaccination and of prior infection with positive PCR test results for SARS-CoV-2 in airline passengers arriving in Qatar. *JAMA*, *326*(2), 185-188. doi: 10.1001/jama.2021.9970 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Pilz, S., Chakeri, A., Ioannidis, J. P. A., Richter, L., Theiler-Schwetz, V., Trummer, C., Krause, R., Allerberger, F. (2021). SARS-CoV-2 re-infection risk in Austria. *European Journal of Clinical Investigation*, *51*(4), 1-7. doi: 10.1111/eci.13520 (previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Breathnach, A. S., Duncan, C. J. A., El Bouzidi, K., Hanrath, A. T., Payne, B. A. I., Randell, P. A., Habibi, M. S., Riley, P. A., Planche, T. D., Busby, J. S., Sudhanva, M., Pallett, S. J. C. & Kelleher, W. P. (2021). Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies. *The Journal of Infection*, *83*(2), 237-279. doi: 10.1016/j.jinf.2021.05.024 (0.86% of previously infected population in London became reinfected); Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2*(7), 100355 (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered COVID patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

[19] Abu-Raddad, L. J., Chemaitelly, H., Coyle, P., Malek, J. A., Ahmed, A. A., Mohamoud, Y. A., Younuskunju, S., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Butt, A. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Yassine, H. M., Al Kuwari, M. G., Al Romaihi, H. E., Al-Thani, M. H., Al Khal, A., Bertollini, R. (2021). SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. *EClinicalMedicine*, *35*, 1-12. doi: 10.1016/j.eclinm.2021.100861 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Hall, V. J., Foulkes, S., Charlett, A., Atti, A., Monk, E. J. M., Simmons, R., Wellington, E., Cole, M. J., Saei, A., Oguti, B., Munro, K., Wallace, S., Kirwan, P. D., Shroti, M., Vusirikala, A., Rokadiya, S., Kall, M., Zambon, M., Ramsay, M., Hopkins, S. (2021). SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study. *The Lancet*, *397*(10283), 1459-1469. doi: 10.1016/S0140-6736(21)00675-9 (finding "a 93% lower risk of COVID-19 symptomatic infection… [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Hanrath, A. T., Payne, B., A., I., & Duncan, C. J. A. (2021). Prior SARS-CoV-2 infection is associated with protection against

that natural immunity provided equivalent if not better protection than vaccine immunity in preventing COVID-19 infection, morbidity, and mortality.[20] Of the 187,549 unvaccinated persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age. Another study, analyzing data from Italy found that only 0.31% of COVID-recovered patients experienced a reinfection within a year after the initial infection.[21]

17. Variants do not escape the immunity provided by prior infection with the pre-variant virus or vaccination.[22, 23, 24] This is true of the delta variant as well. In a study of a large population of patients in Israel, *vaccinated* people who had not been previously infected were 13 times higher

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symptomatic reinfection. *The Journal of Infection*, *82*(4), e29-e30. doi: 10.1016/j.jinf.2020.12.023 (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

[20] Goldberg, Y., Mandel, M., Woodbridge, Y., Fluss, R., Novikov, I., Yaari, R., Ziv, A., Freedman, L., & Huppert, A. (2021). Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2.vaccine protection: A three-month nationwide experience from Israel. *medRxiv*, Preprint. doi: 10.1101/2021.04.20.21255670

[21] Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

[22] Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2,* 100355.

[23] Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A. & Edwards, D. K. (2021). mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. *bioRxiv*, Preprint. doi: 10.1101/2021.01.25.427948

[24] Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T. C. & Tobian, A. A. (2021). $CD8^+$ T-cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants. *Open Forum Infectious Diseases 8*(7), ofab143.

odds of experiencing a breakthrough infection with the Delta variant than patients who had recovered from COVID but were never vaccinated.[25] They had 27 times higher odds of experiencing subsequent symptomatic COVID disease and 7 times higher odds of hospitalization. The design of this Israeli study was particularly strong – it tracked large cohorts of people over time from the time of vaccination or initial infection, and thus carefully distinguished the effect of time since initial exposure or vaccination in estimating its effect estimates. This is important because both vaccine-mediated and infection-mediated protection against subsequent infection diminish with time.

18. In summary, the overwhelming conclusion of the pertinent scientific literature is that natural immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

19. Furthermore, based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting. A survey article published on June 30, 2021, in the *British Medical Journal* concluded, "[t]here is reason to think that immunity could last for several months or a couple of years, at least, given what we know about other viruses and what we have seen so far in terms of antibodies in patients with COVID-19 and in people who have been vaccinated."[26]

20. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 (the virus that causes SARS) and other respiratory viruses. According to a

[25] Gazit, S., Shlezinger, R., Perez, G., Lotan, R., Peretz, A., Ben-Tov, A., Cohen, D., Muhsen, K., Chodick, G. & Patalon, T. (2021). Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections. *medRxiv*, Preprint. doi: 10.1101/2021.08.24.21262415

[26] Baraniuk, C. (2021). How long does covid-19 immunity last? *The British Medical Journal*, *373*, 1-3. doi: 10.1136/bmj.n1605.

paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells 17 years after infection during the 2003 epidemic.[27] A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain—some 90 years later.[28]

21. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, the researchers argue that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.[29]

22. A study from Qatar by Chemaitelly and colleagues (recently published in the New England Journal of Medicine), which tracked 927,321 individuals for six months after vaccination concluded that the Pfizer vaccine's "induced protection against infection appears to wane rapidly after its peak right after the second dose, but it persists at a robust level against hospitalization and death for at least six months following the second dose."[30]

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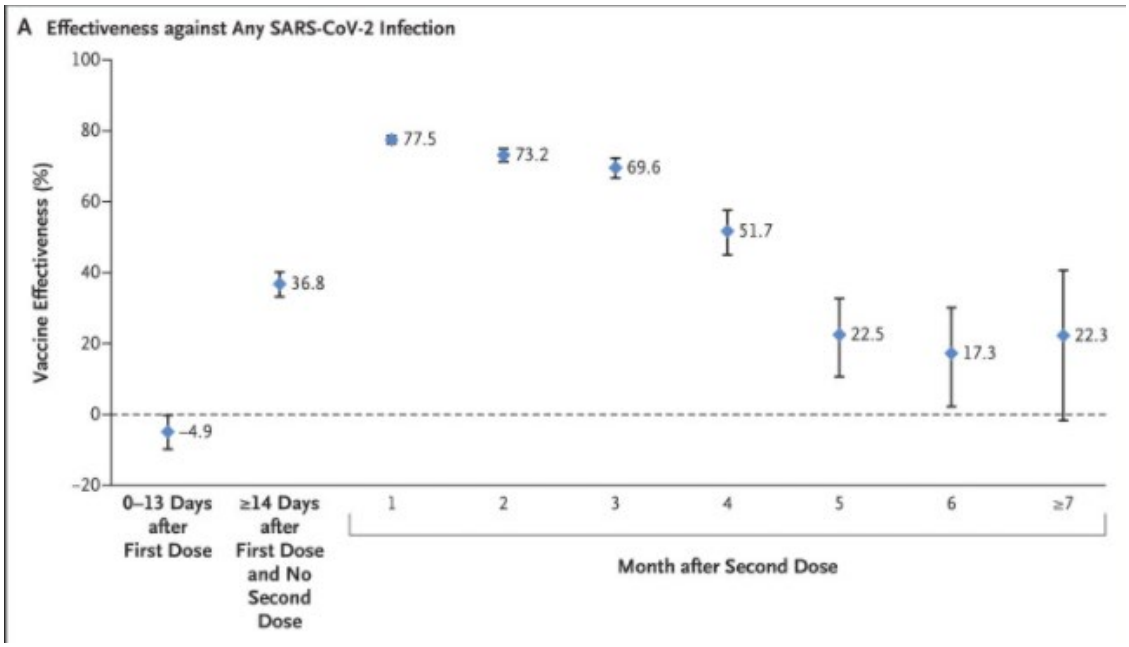
[27] Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. *Nature*, *584*, 457-462. doi: 10.1038/s41586-020-2550-z

[28] Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, *455*, 532-536. doi: 10.1038/nature07231

[29] Ledford, H. (2021). Six months of COVID vaccines: What 1.7 billion doses have taught scientists. *Nature*, *594*(7862), 164-167. doi: 10.1038/d41586-021-01505-x (study notes that "Six months is not much time to collect data on how durable vaccine responses will be. . . . In the meantime some researchers are looking to natural immunity as a guide.").

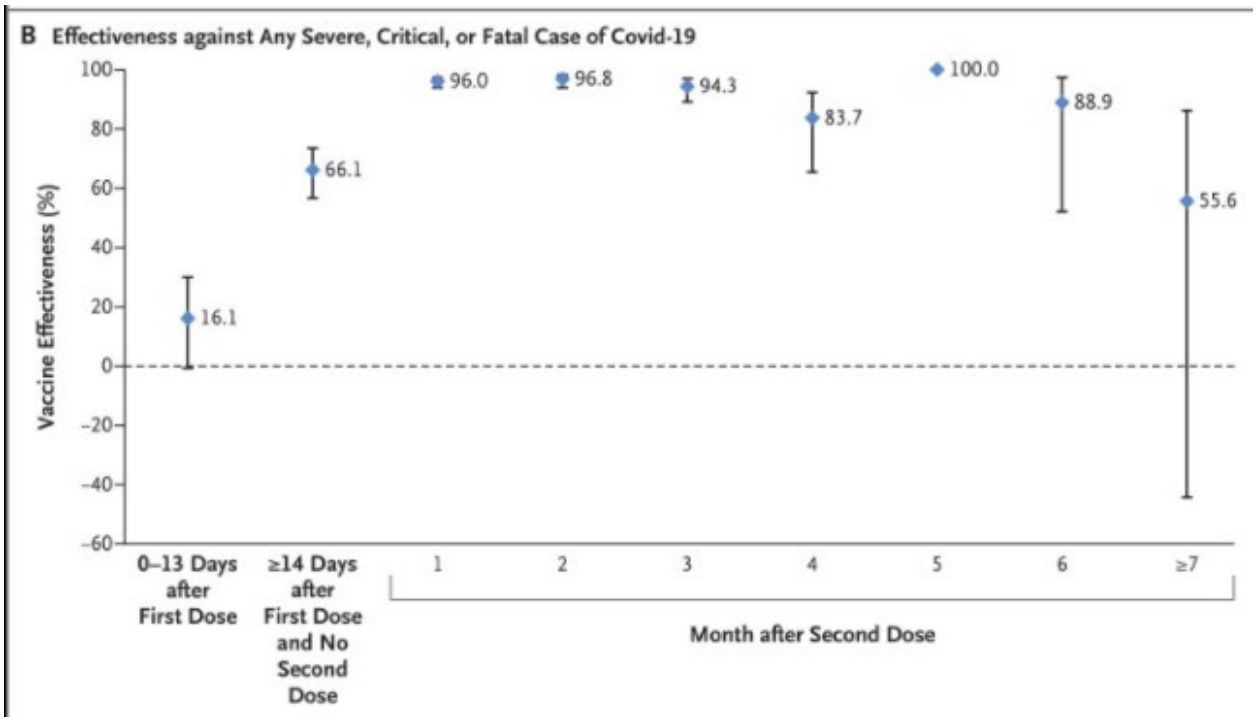
[30] Chemaitelly H, Tang P, Hasan MR, AlMukdad S, Yassine HM, Benslimane FM, Al Khatib HA, Coyle P, Ayoub HH, Al Kanaani Z, Al Kuwari E, Jeremijenko A, Kaleeckal AH, Latif AN, Shaik RM, Abdul Rahim HF, Nasrallah GK, Al Kuwari MG, Al Romaihi HE, Butt AA, Al-Thani MH, Al Khal A, Bertollini R, Abu-Raddad LJ. Waning of BNT162b2 Vaccine Protection

23. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine mediated protection against infection peaks at 77.5% one month after the second dose, and then declines to 22.5%, five months after the second dose. According to this result, vaccines effectively protect against infection (and therefore disease spread) for a short period of time after the second dose of the mRNA vaccines.

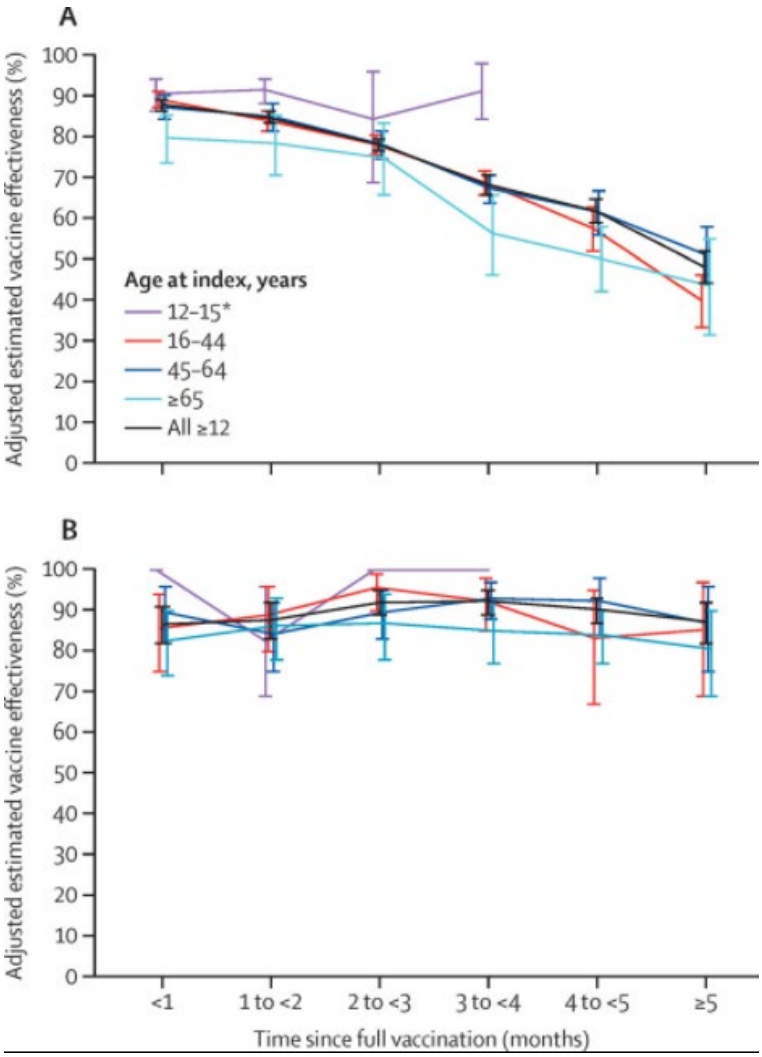


24. On the other hand, Panel B shows that protection versus severe disease is long lasting after vaccination—even though the person will no longer be fully protected against infection and, presumably, disease spread. At 6 months after the second dose, the vaccine remains 88.9% efficacious versus severe disease. While it appears to dip at 7 months to 55.6% efficacy, the confidence interval is so wide that it is consistent with no decrease whatsoever even after 7 months.

against SARS-CoV-2 Infection in Qatar. N Engl J Med. 2021 Oct 6:NEJMoa2114114. doi: 10.1056/NEJMoa2114114. Epub ahead of print. PMID: 34614327; PMCID: PMC8522799.


B Effectiveness against Any Severe, Critical, or Fatal Case of Covid-19
Vaccine Effectiveness (%)
100
80
60
40
20
0
−20
−40
−60
16.1
66.1
96.0
96.8
94.3
83.7
100.0
88.9
55.6
0–13 Days after First Dose
≥14 Days after First Dose and No Second Dose
1
2
3
4
5
6
≥7
Month after Second Dose

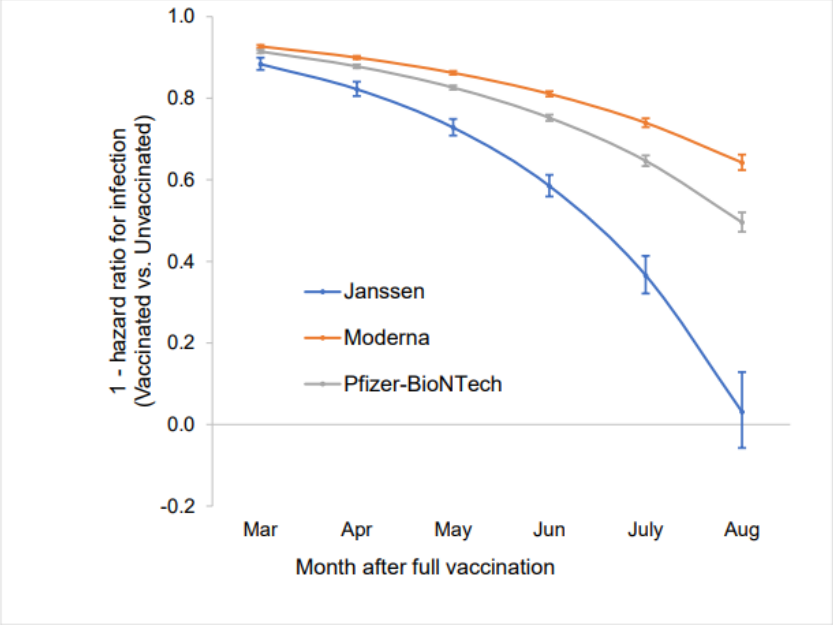
25. The Qatari study is no outlier. A large study in California tracked the infection rates for nearly 5 million patients vaccinated with two doses of the Pfizer mRNA vaccine. The study tracked both SARS-CoV-2 infections as well as COVID-19 related hospitalizations. The figure immediately below plots the trend in vaccine efficacy over time for different age groups in the population cohort. **Panel A** on the right plots effectiveness versus SARS-CoV-2 *infections*.[31] Though the drop in effectiveness is not as steep as in the Qatari study, there is nevertheless a sharp drop. While in the first month, vaccine effectiveness is near 90% for all age-groups, by month 5, it drops to nearly 50% for all the groups. By contrast, **Panel B** plots vaccine efficacy versus *hospitalizations*. It remains high with no decline over time –near 90% throughout the period. The vaccine provides durable private protection versus



[31] Tartof SY, Slezak JM, Fischer H, Hong V, Ackerson BK, Ranasinghe ON, Frankland TB, Ogun OA, Zamparo JM, Gray S, Valluri SR, Pan K, Angulo FJ, Jodar L, McLaughlin JM. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *Lancet*. 2021 Oct 16;398(10309):1407-1416. doi: 10.1016/S0140-6736(21)02183-8. Epub 2021 Oct 4. PMID: 34619098; PMCID: PMC8489881.

severe disease, but declining protection versus infection (and hence transmission).

26. Another recent study tracked 620,000 vaccinated U.S. veterans to measure breakthrough infections for the three vaccines in common use in the U.S.[32] Like the other studies, the authors of the study found a sharp decline in vaccine effectiveness versus infection. Five months after vaccination, the effectiveness of the J&J vaccine dropped from ~90% to less than 10%; the Pfizer vaccine dropped from ~90% to ~50%; and the Moderna dropped from ~90% to ~65%. The figure on this page tracks the decline in effectiveness of the vaccines against infection over time documented in this study. This study corroborates yet another study that documented declining vaccine efficacy in the first three months after vaccination against disease transmission in the era of the Delta variant.[33]



[32] Cohn BA, Cirillo PM, Murphy CC, et al. Breakthrough SARS-CoV-2 Infections in 620,000 U.S. Veterans, February 1, 2021 to August 13, 2021. medRxiv. October 14, 2021. https://doi.org/10.1101/2021.10.13.21264966;

[33] Eyre, D. W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K. B., Walker, A. S. & Peto, T. E. A. (2021). The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *medRxiv*, Preprint. doi: 10.1101/2021.09.28.21264260

27. Yet another study conducted in Wisconsin confirmed that vaccinated individuals can shed infectious SARS-CoV-2 viral particles.[34] The authors analyzed nasopharyngeal samples to check whether patients showed evidence of infectious viral particles. They found that vaccinated individuals were at least as likely as unvaccinated individuals to be shedding live virus. They concluded:

> Combined with other studies these data indicate that vaccinate and unvaccinated individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons.

28. A recent study in the U.K. during its wave of Delta COVID cases compared the likelihood of a vaccinated individual passing on the disease to someone within their same household relative to unvaccinated patients.[35] This study tracked these groups of patients over time to the point they tested positive for COVID. At that point, study investigators measured levels of the SARS-CoV-2 virus in the patients, and observed whether the patients passed on the disease to other household members. The authors find that while vaccination does reduce the fraction of time that a patient passes the disease on to household members from 38% [95% confidence interval: 24-53] to 25% [95% confidence interval: 18-33], there was no statistically significant difference (p=0.17). They conclude:

> Vaccination reduces the risk of delta variant infection and accelerates viral clearance. Nonetheless, fully vaccinated individuals with breakthrough infections have peak viral load

[34] Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Halfmann, P. J., Segaloff, H. E., Kocharian, A., Florek, K. R., Westergaard, R., Bateman, A., Jeppson, G. E., Kawaoka, Y., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Shedding of infectious SARS-CoV-2 despite vaccination. *medRxiv*, Preprint. doi: 10.1101/2021.07.31.21261387

[35] Singanayagam A, Hakki S, Dunning J, et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study [published online ahead of print, 2021 Oct 29]. Lancet Infect Dis. 2021;doi:10.1016/S1473-3099(21)00648-4

> similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts.

29. The CDC recognizes the importance of natural immunity in its updated science brief analyzing the difference in immunity from infection-induced and vaccine-induced immunity.[36] The CDC noted that "confirmed SARS-CoV-2 infection decreased risk of subsequent infection by 80–93% for at least 6–9 months," with some studies showing "slightly higher protective effects (89-93%)." It also noted that "researchers have predicted that the immune response following infection would continue to provide at least 50% protection against reinfection for 1–2 years following initial infection with SARS-CoV-2 or vaccination. This would be similar to what is observed with seasonal coronaviruses."

30. The CDC science brief does claim that vaccine-induced immunity is stronger than immunity from natural infection.[37] This study the CDC relies on to support this claim is not determinative for several reasons.[38] First, its result is contrary to the weight of other evidence, as set forth above. Second, the study compared hospitalization of those infected—and had natural immunity—90-225 days after their infection while against those who had completed their RNA vaccine regime 45-213 days before reinfection. Because immunity—regardless of how gained—wanes over time, the failure to adequately compare like periods means that the study's conclusions are biased in favor of vaccine-induced immunity. Indeed, the study admits this weakness. Third, the study design itself does not permit it to address the critical question of interest – whether

[36] CDC, Science Brief: SARS-CoV-2 Infection-Induced and Vaccine-Induced Immunity (updated Oct. 29, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html#anchor_1635539757101

[37] *Id.*

[38] Bozio CH, Grannis SJ, Naleway AL, et al. Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021.

COVID-recovery without vaccination or vaccination without COVID-recovery provides stronger protection against COVID-related hospitalization. The study analyzes only patients who are already in the hospital. To obtain an accurate answer to the question of interest, it would need to include and analyze patients before entering the hospital. As it is, the study implicitly and incorrectly assumes that the set of hospitalized patients with COVID-like symptoms is representative of the population at large, which is untrue.

31. In summary, the evidence to date strongly suggests that while vaccines—like natural immunity—protect against severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread. In short, there is no medical or scientific reason to believe that vaccine immunity will prove longer-lasting immunity than natural immunity, much less more durable immunity.

III. The CDC's Recommendation for Vaccination of Recovered COVID Patients Applies with Equal Force to Those Who Have Been Previously Vaccinated, Whose Protection Against Infection Wanes Within a Few Months After Vaccination.

32. The CDC, in the Frequently Asked Questions (FAQ) section of its website encouraging vaccination, provides the following advice to previously recovered patients:[39]

> Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

33. The text of this advice by the CDC does not address any of the scientific evidence included here about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that I do not know how long natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will last for years.[40] Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID-recovered patients from vaccination mandates, since the same can be said about vaccine mediated immunity. I do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

34. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine

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[39] Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2019 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

[40] Patel, N. V. (2021, January 6). *Covid-19 immunity likely lasts for years*. MIT Technology Review. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/

breakthrough infections itself recognizes.[41] On the same CDC FAQ webpage I cite above,[42] the CDC writes about vaccine-mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

35. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who *already* has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the CDC's statement in the FAQ is irrelevant. Here again, the possibility of reinfection does not alter the conclusion that, especially for those who have already recovered from COVID, accommodations can be allowed without threatening public safety.

[41] CDC COVID-19 Vaccine Breakthrough Case Investigations Team. (2021). COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. *Morbidity and Mortality Weekly Report (MMWR)*, *70*(21), 792-793. doi: http://dx.doi.org/10.15585/mmwr.mm7021e3

[42] Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

IV. Conclusion

36. Based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable (or more) as that acquiredthrough vaccination. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date.

37. Based on my analysis of the existing medical and scientific literature, any policy regarding vaccination that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.[43]

38. Indeed, now that every American adult, teenager, and child five and above has free access to the vaccines, the case for a vaccine mandate is weaker than it once was. Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero. At the same time, natural immunity provides benefits that are at least as strong and may well be stronger than those from vaccines.

39. I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct.

[43] Bhattacharya, J., Gupta, S. & Kulldorff, M. (2021, June 4). *The beauty of vaccines and natural immunity.* Smerconish Newsletter. https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity

Executed this 20th day of December, 2021, at Stanford, California.

Respectfully submitted,

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Stanford University